



**Government of
Maharashtra**

**Maharashtra Employees State Insurance Society Hospital,
Thane**

(An Autonomous Body of Govt. of Maharashtra registered under Reg. No. GBBSD 488/2019 & F-75443 (M) and Approved by Govt. of India vide letter dt. 25-10-2019)

Office of the Medical Superintendent

Road No. 33, Wagale Estate, Thane 400604

Phone No. 022 20810612/ 20810622

Email: thane.esis@gmail.com

No.TGH/MH-ESIS/Med.Store/ Tab. Rabeprazole Not standard quality/ **6561-63** /2025/Date: **29 AUG 20**

To,

The Director General,
Employees' State Insurance Corporation (ESIC),
New Delhi.

Subject: Intimation Regarding "Not of Standard Quality" Drug Sample
– Rabeprazole 20 mg (Rabidoc-20 Tablet) – Batch No. F4L0950

Respected Sir,

This is to bring to your kind notice that the Drug Inspector, CDSCO (West Zone), Mumbai has drawn a sample of **Tab. Rabeprazole Gastro-resistant Tablet IP 20 mg (Rabidoc-20 Tablet)** manufactured by **Morepen Laboratories Ltd., Batch No. F4L0950, Expiry Date: November 2026** from **MH-ESI Society Hospital, Thane.**

As per the laboratory test report received from CDSCO, the said sample has been declared "**Not of Standard Quality (NSQ)**".

In this regard, we are enclosing herewith a copy of the **test report and related documents** for your kind perusal and necessary action at your level.

Enclosures:

1. Copy of CDSCO Test Report
2. Copy of Covering Letter from CDSCO

We request you to kindly take note of the same and issue further directions as deemed appropriate.

With regards,

Dr. V K. Naik
Medical Superintendent
MH-ESI Society Hospital, Thane

Copy to:

1. Commissioner, MH-ESI Society, Mumbai
2. M/s Morepen Laboratories Ltd

भारत सरकार
केन्द्रीय औषध मानक नियन्त्रण संगठन
पश्चिम खण्ड
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
चौथा तल, झोनल एफ.डी.ए. भवन
जी.एम.एस.डी. कम्पाउंड, बेलासीस रोड
मुम्बई सेन्ट्रल, मुम्बई-400008
ISO 9001:2015 Certified



मन्त्रमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
WEST ZONE
Directorate General of Health Services
Ministry of Health and Family Welfare
4th Floor, Zonal FDA Bhawan, GMSD Compound
Bellasis Rd, Mumbai Central, Mumbai-400 008
Tel: (+91-22) 2300 2215, 2300 2279
Fax : (+91-22) 2300 2271
Email: wzmumbai@cdsco.nic.in

By Regd./Speed Post

F. No.: 4-1/WZ-2025/MG/981

Date: 22.08.2025

To

Mr. Datir R. B. (Pharmacist)
Maharashtra Employees State Insurance Society Hosp.
Road No. 33, Wagle estate, Thane (W)- 400604,
Maharashtra
Ph No: 9890593464
Email Id: rahul1pharma@gmail.com

Subject: Drug reported as **Not of Standard Quality** Drug: Rabeprazole Gastro-resistant Tablets IP 20 mg (Rabidoc-20 Tablets), B. No. F4L0950, D/M: DEC-2024, D/E: NOV-2026, Mfg by M/s Morepen Laboratories Ltd., Unit V, Plot 12C Sector -2, Parwarnoo, Dist.- Soaln HP - 173220- regarding.

Sir,

The subject drug sample was drawn by undersigned Drugs Inspector of this office from your premises i.e. M/s Maharashtra Employees State Insurance Society Hosp., Road No. 33, Wagle estate, Thane (W)- 400604, Maharashtra on 26.06.2025 under section 23 of the Drugs & Cosmetics Act, 1940 and Rules made thereunder and was sent for test and analysis at Central Drugs Testing Laboratories (CDTL), Mumbai.

The subject drug has been declared as "**Not of Standard Quality**" by Government Analyst, Central Drugs Testing Laboratory, Mumbai vide test report No. MUM/LS/2025-26/454 dated 14.08.2025 in Form 13 as the sample does not conform to I.P. 2022 with respect to test for "**Dissolution**". A original copy of test report enclosed herewith.

As per Section 18 a(i) of the Drugs & Cosmetics Act, 1940, no person shall himself or by any other person on his behalf manufacture for sale (or for distribution), or sell or stock or exhibit (or offer) for sale, or distribute any drug which is not of standard quality.

You are required to disclose the name/address and other particulars of the person/firm from whom subject drug was obtained as required under Section 18-A of the Drugs and Cosmetics Act 1940 and furnish the relevant documents as required under Section 18-B of the Drugs and Cosmetics Act 1940. Further, you are requested not to use subject batch of the Drug and recall the same in the greater public interest.

You are also required to submit the following information along with certified copies of the requisite documents as required under section 22(1)(cca) of the Drugs & Cosmetics Act, 1940.

1. The quantity of the subject drug procured and used.
2. The source from whom subject Drug was obtained with relevant copies of documents, purchase invoice etc.
3. Further, directed not to use subject batch of the Drug and recall the same in the public interest and intimate the hold/recall the stock (if any) to this office.

A copy of original report of Government analyst, Central Drugs Testing Laboratories (CDTL), Mumbai in Form 13 is enclosed herewith as required under section 25(2) of the Drugs & Cosmetics Act, 1940.

You are required to furnish the aforesaid information within 7 days for taking further action in this regard.

You are requested to acknowledge the receipt.

Thank You,

MANOJ
NILKANT
GAMBHIRE

Digitally signed by
MANOJ NILKANT
GAMBHIRE
Date: 2025.08.22
17:12:18 +05'30'

(Dr. Manoj Nilkant Gambhire)
Drugs Inspector
CDSCO, West Zone, Mumbai

Enclosure: Copy of Government Analyst report No. MUM/LS/2025-26/454 dated 14.08.2025 in Form 13

Copy:

- 1) The Medical superintendent, Maharashtra Employees State Insurance Society Hosp. Road No. 33, Wagle estate, Thane (W)- 400604, Maharashtra - **For giving necessary directions to stop further use of subject NSQ batch of the Drugs & its recall**
- 2) M/s Morepen Laboratories Ltd., Unit V, Plot 12C Sector -2, Parwarnoo , Dist.- Soaln HP - 173220
- 3) Deputy Drugs Controller (I), CDSCO (WZ), Mumbai



FORM 13
(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER
SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received : Mr. Manoj Nilkant Gambhire ,Drugs Inspector
West Zone -1 Mumbai CDSCO (West Zone-1) 4th Floor
Zonal FDA Bhawan, GMSD Compound, Bellasis Road,
Mumbai Central, Mumbai-400008 (India)
2. Serial No. and date of Inspector's memorandum : 3-4/MG/CDTL-Mum/WZ/2025/596 , 26-JUN-2025
3. Number of Sample : LSWZ/MG/2025/21
4. Date of receipt : 27-JUN-2025
5. Names of drugs purporting to be contained in the sample : Rabeprazole Gastro-resistant Tablets IP 20 mg
(Rabidoc-20 Tablets)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/MUM/2025-26/0180	MUM/LS/2025-26/454	F4L0950	Dec-2024 Nov-2026	NA	Morepen Laboratories Ltd., Unit V, Plot 12C Sector -2, Parwarnoo , Dist. - Soaln HP - 173220.

6. Condition of seals on (the packet or on portion of sample or container) : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector

7. Result of test or analysis with protocols or test or analysis applied : Please see below
 Date of Testing : From 25-Jul-2025 To 12-Aug-2025

COMPOSITION : Each enteric coated tablet contains:
 Rabeprazole Sodium IP 20 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Peach coloured, circular, biconvex, enteric coated tablet, packed in alu-alu blister strip supplied in paper carton.	NA
2	Identification	Gives positive test for Rabeprazole Sodium	NA
3	Dissolution	Acid stage : Complies Buffer stage : Does not comply	
	S1	Release of each individual unit obtained is as follows: Unit 1 : 66.76 %, Unit 2 : 62.88 %, Unit 3 : 66.09 %, Unit 4 : 63.93 %, Unit 5 : 65.97 %, Unit 6 : 67.21 % All units less than; 70 % of label claim : - Limit 75 % of label claim	Each unit is not less than Q + 5 (i.e. 75 %) Q is 70 %

	S2	Release of each individual unit obtained is as follows: Unit 1 : 65.95 %, Unit 2 : 66.10 %, Unit 3 : 64.90 %, Unit 4 : 62.28 %, Unit 5 : 66.75 %, Unit 6 : 62.70 % Average Drug release of 12 units (S1 + S2) is 65.13 % of label claim :- Limit NLT 70 % of label claim	Average of 12 units (S1 + S2) is equal or greater than 70 % (Q) and no unit is less than 55 % of claim (Q - 15 %)
	S3	Release of each individual unit obtained is as follows: Unit 1 : 70.89 %, Unit 2 : 73.46 %, Unit 3 : 63.80 %, Unit 4 : 67.83 %, Unit 5 : 65.56 %, Unit 6 : 69.21 %, Unit 7 : 63.29 %, Unit 8 : 54.26 %, Unit 9 : 61.62 %, Unit 10 : 57.43 %, Unit 11 : 57.83 %, Unit 12 : 56.33 % of label claim Average of 24 units : 63.46 %	Average of 24 units (S1 + S2 + S3) = NLT 70 %
4	Uniformity of content	Complies	NA
5	Average weight	151.08 mg	NA

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Rabeprazole Sodium	18.98 mg/ tab	20.0 mg/ tab	94.9	90.0 to 110.0 % of label claim	I.P. 2022

In the opinion of the undersigned the sample referred to above is not of standard quality as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

The sample does not conform to I.P. 2022 with respect to test for "Dissolution".

Signature
14/08/25
एस. ए. नवरत्ने / S. A. NAVARATNE
वरिष्ठ वैज्ञानिक सहायक एवं सरकारी विश्लेषक
SENIOR SCIENTIFIC ASSISTANT & GOVT. ANALYST
केंद्रीय औषधि परीक्षण प्रयोगशाला
CENTRAL DRUGS TESTING LABORATORY
मुंबई / MUMBAI

Date: 14-AUG-2025

GOVERNMENT ANALYST

Report in the red colored paper indicates the sample is not of standard quality.

----- END OF REPORT -----

DRUGS STANDARD CONTROL ORGAN